IN THE UNITED STATES DISTRICT COURF LERKS OFFICE DISTRICT OF MASSACHUSETTS

BOSTON DIVISION 201 CEP 24 PM 12: 17

THE UNITED STATES OF AMERICA

TAD TAYLOR, PLAINTIFF	S CIVILLOCE OF LAINT
v.	99999999999999999999999999999999999999
SHIRE PHARMACEUTICALS, INC., DEFENDANT	S CASE No.:
	*** DEMAND TO PROCEED TO JURY TRIAL ***

CIVIL COMPLAINT SEEKING DAMAGES UPON LEARNED INTERMEDIARY
CITING DEFECTIVE PRODUCT CLAIM, FAILURE TO WARN CLAIM, FORESEFABLE DANGERS CLAIM
ALL UPON MANUFACTURER'S DUTY TO DISCLOSE RISK FACTORS, AND PROMOTE CAUTIONARY PRESCRIBING

COMES NOW, MOVANT, TAD TAYLOR (hereafter "Plaintiff"), and all as more formally represented in propria personam, sui juris, and acting on his own behalf and as his own legal counsel, hereby moves this Honorable United States District Court upon Diversity Jurisdiction, to consider violations, deficiencies, misrepresentations, misleading promotional materials, aggressive sales and marketing tactics, and deceptive trade practices, all designed to fraudulently promote the safety, efficacy, and convenience of opioid prescribing in an effort to stimulate physician prescription conveyance thus resulting in a compromised environment within the physician's practice leading to violations of compliance, legal standing, and of course, patient safety. See; Talton v. Arnall Golden Gregory, LLP, 276 Ga.App. 21, 27n.7, 622 S.E.2d 589 (2005), also see; Jack v. Glaxo Wellcome, Inc., 239 F.Supp. 2d 1308, 1321 (2002), and finally, see; State of Massachusetts v. Purdue, State of New York v. Purdue-Abbott, and McCallister v. Purdue Pharma L.P., 164 F.Supp. 2d 783 (2019), (2020), and finally (2001), respectively.

Damages to this Plaintiff as a previously practicing pain medicine physician, shall include, but shall not be limited to, damaged reputation, foregone license, lost income, missed opportunity, seized investments and assets, loss of freedom, stress and anxiety.

An accompanying memorandum of law and precedence shall be included contemporaneously herewith.

JURISDICTIONAL SIGNIFICANCE

LET THIS HONORABLE COURT TAKE NOTICE THAT;

I, Tad Taylor, as named Plaintiff to this Civil Matter, hereby affirm that, this Honorable Court shall have and hold personal and subject-matter jurisdiction, and that such coram judice shall remain sufficient upon Diversity Jurisdiction, all as further described herein. Such jurisdictional significance shall qualify under Title 18 U.S.C. §3731 providing venue and true and complete, and as such, divesting all other Courts of their interest in matters thereof. See; <u>Griggs v. Provident,459</u> U.S. 56 (2001).

DIVERSITY JURISDICTION

UPON SUCH SPECIAL CONDITIONS OF MULTI-STATE DIVERSITY;

I, Tad Taylor, as named Plaintiff to this Civil Complaint, hereby affirm that I am a resident of the State of Texas, County of Dallas, and residing at Federal Correctional Institution in Seagoville, Texas 75159 upon filing this Civil Complaint within an Article III United States District Court outside of my state and purview, and as such, requiring special dispensation to proceed under Diversity Jurisdiction as set forth upon Title 28 U.S.C. §1332(a), and as further defined upon Texas Civil Code and Legal Code Annotated, including, Title 2 and Sections §\$16.002 and 16.003.

In addition, and in accordance with Civil Procedure, this appeal for Diversity Jurisdiction is further predicated upon a Civil Claim exceeding \$75,000.00 as an additional prerequisite to Diversity requirements and cases citing Deceptive Trade Practice. May this Court extend Diversity Jurisdiction and accept this proceeding as sound and viable jurisdiction to proceed.

Under the guise of Title 28 U.S.C. §1441(a), a filing within Federal Court shall be permitted if there is diversity of citizenship between the parties pursuant to Title 28 U.S.C. §1332(a), and upon the federal question jurisdiction statute under §1331. In this instant Claim, there exists (1) complete diversity upon claiming both fraudulent joinder and misjoinder of non-diverse defendants, AND (2) the existence of suplemental jurisdiction, specifically citing the FDCA, 21 U.S.C. §321 which governs the manufacturer and distribution of various opioids, and 21 C.F.R. §10.30 providing guidance on issues relating to prescribing information and deceptive trade.

LEGAL STANDING OF PLAINTIFF

LET ALL MEN KNOW BY THESE PRESENTS THAT;

I, Tad Taylor, as named Plaintiff to this Cause, hereby declares and decrees that I am a "flesh and blood" adult male "PERSON" and not a corporation or other such entity as required by definition upon Rules of Civil Procedure in representation of a Complaint brought against the named Defendant(s), and that, in accordance with the Color of Law and this Plaintiff's Constitutional Right to bring forward such Complaint before an Article III United States District Court, such standing as "PERSON" shall be afforded all rights of Due Process upon request to proceed to Jury Trial.

PREVIOUS LEGAL ACTION

THIS COURT MAY TAKE NOTICE THAT;

I, Tad Taylor, as named Plaintiff to this Cause, hereby affirms and attests that, in accordance with Civil Procedure, this Court shall be entitled to a formal statement confirming that this Plaintiff has NEVER filed a formal complaint or Civil Lawsuit against the named Defendant(s), and this Plaintiff has NO other legal filings pending in relation to this specific matter and Cause.

STATUTE OF LIMITATIONS

LET THIS HONORABLE COURT AFFIRM THE FOLLOWING;

Plaintiff, upon civil complaint under State Code and Federal Statute, affirms that he would otherwise be barred from formal proceeding upon expiration of the standard term of limitation prescribed as Two (2) years from the date of injury, except upon cases of "continued violation" whereupon such Damages are still being experienced. The Doctrine of Continuing Violation sets forth an extension of the Statute of Limitations oninfinitis. See; Wallace v. Kato, 549, U.S. 384, 387, 127 S.Ct. 1091, 166 L.Ed. 2d 973 (2007).

It shall stand upon this instant case that the Plaintiff has filed in accordance with the Statute of Limitations of Two years, yet continues to suffer with Damages resulting from the Deceptive Trade Practices and Fraud brought upon him by and through the named Defendant(s) to this Cause. See; <u>Piotrowski v. City of Houston</u>, 237 F.3d 567, 576 (5th Cir. 2001).

This Claim shall accrue when the Plaintiff experiences "a complete and present cause of action," or "when the Plaintiff can file suit and obtain relief." See; Walker v. Epps, 550 F.3d 407, 414 (5th Cir. 2008).

For these reasons, this Plaintiff avers that he remains within the Statute of Limitations to proceed with this filing and Complaint.

PLAINTIFF CREDENTIALS AND EXPERTISE:

It shall stand that the Plaintiff maintained expertise and proper licensure that establishes him as qualified to practice pain management upon the Medical Board for the State of Texas. His experience includes that of a former degree in Chemical Engineering as a Ph.D. and having published more than 100 journal and conference white papers. He studied and taught for over two years in Osaka, Japan at the Japan Science and Technology Agency as a Fellow, and also as an associate professor at Okayama University with research through the University of Maryland and Johns Hopkins University. His medical degree is from Yale Medical School and includes positions as an adjunct professor at the University of Texas Medical Branch, Galveston. The Plaintiff has engaged in extensive coursework through the Texas Pain Society and completed a certificate on Safe Opiate Prescribing in February, 2012. He has formally participated in more than twenty lectures on hypertension, diabetes, depression, GERD, and other subjects, and remained renowned in his field as a pain treatment expert. This Plaintiff's prescribing and dosing protocols resulted in NO overdoses and NO deaths, and all such prescribing and formulary protocols followed Manufacturer's offical and published recommendations and the guidelines of pharmaceutical marketing and promotional representatives who advise on contraindications and addiction avoidance.

The Plaintiff managed his patient workload according to a defined schedule based on his ability as a primary triage and diagnosis physician to see each patient and order lab analysis prior to prescribing. As such, this Plaintiff's work schedule consisted of face-to-face triage and diagnosis on approximately six patients per day.

"A qualified expert possesses the necessary knowledge, skill, experience, training, or education relevant to the facts at issue." See; Ralston v. Smith & Nephew Richards, 275, F.3d 965, 969 (10th Cir. 2001). It then shall stand that this Plaintiff was highly qualified, followed complaince protocols, yet relied on deceptive guidance.

STATEMENT OF CLAIM

Tad Taylor, as named Plaintiff to this Cause, affirms and attests that he has suffered extensive Damages at the hands of the named Defendant(s) upon their failure to meet a professional duty of standards and practices designed to safeguard both the representative physician prescribing the Defendant's manufactured drugs and formularies, and the physician's practice upon its dependence on the manufacturer's safety, dosage, and contraindication materials and guidance all to remain in compliance with efficacy and legal standing when prescribing Schedule II narcotics, and specifically, opioids.

Plaintiff Taylor proceeded to rely upon the guidance and advisement of the manufacturer's marketing and sales representatives, its literature and promotional materials, and its scientific, efficacy, and formulary protocols, all of which proved to be misleading, misrepresented, fraudulent, and outside of Drug Enforcement Administration legal compliance guidelines, thus resulting in this Plaintiff violating certain compliance standards, potentially endangering his patient base, and subsequently resulting in a seizure of his practice, his license, and his freedom upon conviction and imprisonment, all while prescribing medications in accordance with the Defendant's recommendations and acceptable dosing levels. Despite this Plaintiff, as a practitioner representing pain patients within the prescribing guidelines provided to him through the manufacturer (Defendant), and in light of a required diagnosis of every patient, established blood and lab analysis before any unauthorized prescribing, and extensive screening which resulted in over 200 discharges, all while prescribing fewer than a maximum of 1.2 grams per patient and two prescriptions compared to a defined "Pill Mill" as prescribing 1,200 grams per patient, yet, even under strict compliance protocols, by following the formulary recommendations and safety standards of the manufacturer, this Plaintiff, as a practicing physician, still fell outside of legal complaince, all as a result of the deceptive trade practices and fraudulent standards presented by Defendants.

FINDING OF FACT

MAY THIS HONORABLE COURT CONSIDER THE FOLLOWING;

- 1. Tad Taylor, hereafter "Plaintiff" avers that he is a "flesh and blood" adult male, "PERSON" and not an organization, corporation, association, or other entity, and that he is currently remanded under the bondage of incarceration with the Federal Bureau of Prisons and residing at Federal Correctional Institution in Seagoville, Texas for a term of Twenty (20) years under Criminal Case 4:17-CR-00009-MAC-CAN upon charges stemming from Conspiracy to Distribute Schedule II, III, IV Controlled Narcotics, and specifically "Opioids" under the auspices of maintaining a "Pill Mill" environment through an alleged illicit conveyance of prescribed medications outside of Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) compliance protocols.
- 2. Plaintiff avers that this Honorable Court shall have and hold sufficient coram judice, including, personal and subject-matter jurisdiction, and all as prescribed under Title 18 U.S.C. §3731 qualifying venue as true and complete, and divesting all other Courts from their interest in matters set forth herein.
- 3. Plaintiff affirms that his case shall qualify under the guise of Diversity Jurisdiction upon a filing against named Defendant(s) residing outside of his home and custody state of Texas, this establishing grounds for diversity that shall also include claims exceeding \$75,000.00, violations of Deceptive Trade Practices by and through the Defendant(s), and infractions involving Interstate Commerce.
- 4. Plaintiff affirms that he has placed Process of Service upon the named Defendant(s) by providing a true and complete copy through the United States Postal Service via First Class mail (postage-paid), all as timely and verified thereof.

- 5. Plaintiff avers that he managed and owned a medical pain clinic within Richardson, Texas between the years 2010 and 2012 where he oversaw the care and diagnosis of a patient base of approximately 1150 patients with 50% to 60% suffering with chronic pain, and approximately 600 receiving treatment for multiple medical ailments. Throughout that practice, the clinic logged NO patient overdoses and NO patient deaths resulting from prescribed drugs issued through the clinic. Of the patient base, nearly all patients were given blood analysis for screening, and all patients were required to receive a personal consult and diagnosis by and through the clinic physician prior to treatment or prescription. As such, all compliance protocols for proper pain clinic therapy were followed and all prescriptions satisfied the prescribing standards and guidelines set forth by the pharmaceutical manufacturer of the medications recommended as part of a treatment plan and formulary.
- 6. Plaintiff maintains a medical license under the State of Texas medical board following his graduation from Yale Medical School, including a Ph.D. in engineering. He is also an adjunct professor at the University of Texas Medical Branch, Galveston. In addition to a multitude of pain management coursework through the Texas Pain Society, the Plaintiff's practice also included receiving guidance and advisement from a series of individuals who visited and reviewed the protocols of the clinic, including, Six (6) Dallas Police Officers, Two (2) Judges, Two (2) Sheriffs, an X-DEA Agent, and Three (3) attorneys, all advising that the clinic acted in good faith and followed compliance protocols in accordance with the Manufacturer's regimen and recommendations.
- 7. Plaintiff avers that when approached by the Texas Medical Board for review of his charts and prescribing history, he remained wholly compliant and was informed that his practice was following protocols in accordance with Manufacturer's approved treatment thresholds and dosage recommendations, however, despite all such compliance findings, DEA Task Force agents raided the clinic upon accusations of a "Pill Mill."

- 8. Upon raid and arrest, the DEA alleged under Discovery of Evidence that the clinic and specifically, Dr. Tad Taylor (as criminal Defendant in case) prescribed excessive amounts of Schedule II, III, and IV controlled substance narcotics beyond proper and reasonable limits based on the number of patients under treatment. The Discovery of tainted evidence confirmed that prosecutors confiscated 1150 patient charts and selected Seven (7) patient prescriptions as exceeding DEA charting limits in accordance with FDA standards, yet the Manufacturer's literature and advisement remained in excess of such standards, and provided the treating physician (Plaintiff) with confidence that his prescribing fell well within charting protocols. In other words, this Physician, now as Plaintiff, remained within the guise and guidance of manufacturer's dosing and prescribing recommendations, thus resulting in this compliant physician placing his patient base in danger upon false, fraudulent, and misleading marketing, promotion, and sales tactics to advance larger quantities of their product.
- 9. Plaintiff maintains medical record evidence that such prescribing protocols remained within the guise of the manufacturer's recommendation, yet fell outside of the DEA's acceptable standards for excessive dosing therefore placing the complicity not on the Plaintiff who had no overdoses and no deaths, but on the Manufacturer (Defendant) who promoted through Deceptive Trade Practices, an overzealous and illegal formulary which, but not for these fraudulent promotional tactics, would have vindicated the Plaintiff of all wrongdoing.
- 10. Plaintiff, as a result of these Deceptive Trade Practices and his subsequent arrest, conviction, and imprisonment, has suffered Damages that include Compensatory; lost income, foregone license, missed opportunities, seized assets and investments, AND Punitive Damages to include; stress, anxiety, nightmares, depression, sleep deprivation, loss of freedom, tarnished reputation, imprisonment, and Post Traumatic Stress Disorder.

HISTORICAL FINDINGS ON OPIOID ABUSE:

Plaintiff, Tad Taylor, brings forward a compelling historicity of the opioid crises, and abuses and fraudulent practices that accompanied the epidemic under the carefree and ubiquitous promotional campaigns designed by and through the pharmaceutical manufacturers to advance prescribing, and to move the product into as many medicine cabinets as possible despite violations of dosage and contraindication protocols. Vested in these compliance issues, pharmaceutical manufacturers, their promotional materials, and the guidance provided by their marketing and sales teams, all contributed to patient addiction, an opioid epidemic, and a rash of arrests and convictions of physicians and medical professionals who were compliant with manufacturer's charts and recommendations, but outside of compliance with FDA and DEA statutory guidelines.

Since the onset of such abuse and deceptive trade practices, Congress has moved to implement federal regulations to address the imperatives affecting proper dosage through regulated labeling, monitoring, and warnings associated with opioid formulary. Prior to such regulatory considerations, physicians relied upon the studies presented to them by and through the manufacturer, thus resulting in a series of physician arrests and convictions at the hands of DEA enforcing guidelines that were never set or adhered to by the manufacturers, thus compromising the integrity of the physician and creating a deceptive trade practice which directed blame at the prescribing medical professional and away from the manufacturer, the real culprit.

Congress has since moved to address "promotional labeling" as discussed under 21 C.F.R. §§314.70(c) and 314.81(b)(3)(i), which, traditionally, has required no advance FDA approval, thus giving the manufacturer liberties to promote false or misleading recommendations, and to avoid dosage warnings or addiction indicators. Until such abuse was brought to the forefront, the Uniform Controlled Substance Act was directed, not at the manufacturers, but rather, upon the prescribing physicians.

DANGERS OF OPIOIDS IGNORED BY MANUFACTURERS:

Plaintiff, Tad Taylor, as an educated, licensed, and experienced physician, wholly understood the inherent dangers of opioid addiction and dependence, and as such, NEVER experienced a patient overdose throughout his tenure, and NEVER experienced a patient death under his watch in prescribing opioids, however, he was arrested, prosecuted and convicted, based on his reliance upon the manufacturer's subsequent charting, dosage recommendations, and guidelines for prescribing, which, did NOT comport with those of the FDA or DEA, thus compromising the integrity of the Plaintiff despite his following all protocols according to manufacturer's recommendation.

Opioids are designed as time release medications, yet, in the instant case, proved to be defective upon their tendency to deliver up to 40% of the medication in the first hour after administration (unreported by manufacturer), and which then results in a tendency to remain in the bloodstream of some people for more than 14 hours (unreported by the manufacturer). These conditions could dramatically alter a patient's reaction to the medication if combined with other medications, and when compared to acceptable dosing standards, were found to conflict with FDA and DEA acceptable dosing standards, thus leading to a compliance violation of the law while remaining within compliance of the manufacturer's findings and recommendations. Expert testimony may easily provide a comparison between manufacturer guidelines and inconsistencies with FDA and DEA guidelines which may result in compliance violations. Such testimony may be introduced upon this Petition moving the Jury Trial where an expert may explain the gatekeeping role and compare that with scientific guidelines. See; Dodge v. Cotter Corp., 328 F.3d 1212, 1221-23 (10th Cir. 2003). is determined by assessing whether the reasoning or methodology underlying...is scientifically valid." See; Hollander v. Sandoz Pharmaceutical, 289 F.3d 1193, 1204 (10th Cir. 2002). Thus, the manufacturer led the physician to slaughter.

MANUFACTURER'S CONTRIBUTION TO COMPLIANCE VIOLATIONS:

Plaintiff avers that the manufacturer's were complicit in their contributions to downplay or misrepresent contraindication and addiction warning recommendations, and to exclude language and dosing protocols designed to minimize indicators of risk.

Such changes and revisions in manufacturer's labeling, were designed to mislead prescribers, such as that of the Plaintiff, by failing to address warnings, precautions, adverse reactions, and other categorical revisions that were established under the guise of the FDA. See; 21 C.F.R. §314.70 and Motius v. Pfizer, 127 F.Supp. 2d 1085 (Central Dist. Cal. 2000). The FDA requires that manufacturers provide warning to health care professionals of any harmful or adverse effects associated with a specific formulary. Such obligations exist under federal regulations, yet often, manufacturers shelter behind the complicity of a frontline gatekeeper (physician) as the legal culprit. See; Geier v. American Honda Motor, 529, U.S. 861, 874-75, 120 S.Ct. 1913, 146 L.Ed. 2d 914 (Supreme Court 2000).

Between 1999 and 2008 alone, more than 450,000 people died from opioid abuse, and since that time, the numbers have skyrocketed to nearly a million. Between 21% and 29% prescribed opioids, end up misusing them due to misleading recommendations. Of those, 12% will develop an opioid disorder and 6% will transition from opioids to heroin, and all as a result of misrepresentations from the manufacturer passed on to prescribing gatekeepers who believe such formularies are within compliance and in accordance with acceptable levels set forth under the FDA. Everyday, roughly 128 people die from an opioid-related overdose, and may resulting from over-consumption that falls within acceptable levels determined by and through the marketing and charting guidelines promoted within the manufacturer's recommended dosage. The Mu receptors of the human central nervous system receives pain releief but excessive dosing leads to a flood of endorphins and a euphoria, the level recommended by the manufacturer. This abuse and misrepresentation compromises both the patient and the prescribing physician.

MANUFACTURER'S DECEPTIVE TRADE PRACTICE AND AGGRESSIVE PROMOTIONAL TACTICS:

Plaintiff, Tad Taylor, as a practicing physician, adhered to strict protocols upon triage, diagnosis, pain evaluation, and prescribing protocols, all in accordance with the standards and recommendations of the manufacturer following FDA approvals.

As such, it has been determined upon precedence set forth through a multitude of other liability lawsuits brought against manufacturers that liability tort depends on the manufacturer's conveyance through its packaging, labeling, distribution, sales, marketing, promotion, education and training, and its charting and guidelines as to that which has been deemed (according the manufacturer) as within compliance and law.

Upon an evaluation of the Defendant's deceptive trade practices and its overzealous sales, promotion, and marketing tactics, prosecutors have determined that the manufacturer has a certain duty to their prescribing physicians to avoide the;

Commission of massive sales forces to push messaging upon prescribers Disseminate branded promotional materials about the convenience of prescribing Design branded messaging which promotes the use of opioids for multiple ailments Employ bias or non-objective "key opinion leader" physicians to promote product Fund professional organizations and credential service boards as key sponsors Entice physicians through promotional events, gifts, seminars, outings, and funds

In the instant case, the Plaintiff, as a prescribing physician, experienced each of these deceptive trade tactics and was compelled to promote opioids in accordance with the manufacturer's safety and prescribing recommendations, all of which resulted in compliance violations under DEA guidelines, therefore, establishing that the named Defendants, and not the Plaintiff, were responsible for compliance violations, and for subsequent damages that befell upon the Plaintiff following his arrest and conviction. See; Beale v. Jones, 210 Va. 519, 171 S.E. 2d 851, 853 (VA 1970), also see; Sugarland Run Homeowners v. Halfmann, 260 Va. 366, 535 S.E. 2d 469, 474 (VA 2000).

The Plaintiff may then provide a sequence of causation between his conviction and the recommendations of the manufacturer whereupon, post hoc, ergo propter hoc, be presented before a jury to link manufacturer causation to physician conviction. For the Plaintiff to prevail, it must then present such findings and evidence before a jury of peers in order to establish causation. See; Beverly Enterprise-Virginia v. Nichols, 441 S.E. 2d 1, 3, 10 Va.LawRep.995, 247 Va. 264 (VA 1994).

The Plaintiff is prepared to introduce at jury trial, the following;

Expert testimony to provide causation between manufacturer recommendation and arrest. Public policy and FDA recommendations exist to prove Mfg's deceptive trade practices. Manufacturer's failure to warn physicians and to ignore the intermediary doctrine. Provide a direct contridiction between Mfg dosing and FDA/DEA dosing guidelines.

In addition to these quantifiable and technical misrepresentations, the manufacturer was also complicit in its aggressive tactics involving the use of coercive and seductive misrepresentations tantamount to promotion opioids in a manner that described them as "over-the-counter" in terms of safety, convenience, and accessablity. Such tactics. and specifically, those employed against the Plaintiff in his Richardson, Texas clinic, included promotional incentives, loyalty gifts, training and seminars, lunches, and a multitude of highly-aggressive sales tactics which were designed to intimidate and to encourage over-prescribing, all as within safe and compliant limits. Such tactics resulted in "over-promotion" of usage, hybrid claims, and were designed to draw on the elements of marketing and efficacy, yet resulted in leading the physician (Plaintiff) into negligent representations and misrepresentations, and over-prescribing, all as a result of deceptive trade practices, failure to warn, misrepresented labeling and unrealistic contraindications, neglected disclosures, and a defective product which was contradictory in terms of its time-relase properties and its addictive significance. This complicity of "over-promoting" product, of "down-playing" risk, and of "deceptive warnings" designed to encourage excessive prescribing, convicts the manufacturer of compromising the integrity of the patient and the physician. See; Buckman v. Plaintiff's Legal Committee, 531 U.S. 341, 121 S.Ct. 1012, 1017, 148 L.Ed. 2d 854 (2001).

Manufacturers like Purdue Pharmaceuticals incentivized hundreds of prescribers and even launched a program called "Evolve to Excellence" with sales directives taunting slogans such as "Sell, Baby, Sell!" Other manufacturers (Defendants) followed suit.

A series of aggressive sales and promotional tactics were employed by manufacturers and programs were implemented to incorporate physician "kick-back" initiatives to further encourage an atmosphere of over-prescribing based on non-compliant guidelines which the physicians believed were vetted. Attorney General Racine affirmed that companies like Purdue Pharmaceutical and its controlling family enterprise, the Sackler Family, "recklessly and unlawfully promoted dangerous drugs and endangered District residents. We've filed suit now to hold them accountable." These sentiments were conveyed against pharmaceutical manufacturers of opioid throughout the country following the Purdue legal challenge and successful adjudication. These companies, and Purdue in particular made over 8,037 visits to various physician practices between 2007 and 2015 alone. manufacturers realized that over 72% of those prescribed opioids would begin with pain management, therefore, pain clinics were highly targeted and referred to as "high-value prescribers" Companies like the Defendant used tactics in which they described undertreated pain as "pseudoaddiction." In fact, under a program described as "Responsible Opioid Prescribing", Purdue and others suggested that pseudoaddicted patients should be treated with higher doses of opioids to solve the problem. This promotional initiative caught the ire of the DEA but convictions resulted in a "low hanging fruit" approach to physician arrests and asset seizures rather than taking on the legal beheamoth of the rich and powerful pharmaceutical manufacturers.

It was then, well within the Manufacturer's control to promote healthy and responsible compliance guidelines, and to warn of contraindications and product defects, yet, all aspects of this defense were ignored and the physician prescribers took the fall. See; Black v. M&W Gear Company, 269 F.3d 1220, 1231 (10th Cir. 2001). Also see; Johnson v. Ford Motor Corp., 2002 OK 24, 45 P.3d 86, 91n 12 (Oklahoma 2002).

The concept of "Learned Intermediary Doctrine" places liability on the manufacturer to protect and indemnify the prescribing physician. It states the Manufacturer has a duty to warn and protect the physician from compliance violations. See; <u>Talton v. Arnall Golden</u> 276 Ga.App. 21, 27 n.7 622 S.E. 2d 589 (2005). Damages resulted from Manufacturer liability

DEFECTIVE PRODUCT AND FRAUDULENT PROMOTION:

Plaintiff, Tad Taylor, as named within this Civil Complaint, and as previously, a practicing physician in the specialty of pain management in relation to his Richardson, Texas clinic, brings forward certain abuses and misrepresentations practiced by and through the officers, assigns, employees, and agents of Defendant, Shire Pharmaceuticals, Inc., upon which, this Plaintiff suffered harm, injury, and damages all associated with such abuse therein.

Shire Pharmaceuticals, Inc., the manufacturer and marketing arm for a certain prescribed schedule II controlled substance known under the trade name, ADDERALL, has violated its duty of standards and ethics having produced and marketed a defective opiod analgesic which is designed to activate through a time-release schedule, and which, according to researchers associated with the Opiod Analgesic Risk Evaluation and Mitigation Strategy (REMS) forum, found that such time-release component proved to activate far earlier and present more robust than that which is displayed on all marketing materials, or that which is supported upon the counsel and advisement of company marketing representatives.

This defective time-release component and the significance of cytochrome inhibitors which have a likelihood of increasing oxycodone plasma concentrations through use, and even, recommended use and protocol formulary by the manufacturer, exceeds FDA testing and approvals, and places those prescribers (Plaintiff) in a compromised position thus damaging the integrity of the prescribing physicians, placing his patient base at risk, and generating a prescription manifest that, in this instant case, caught the ire of the Drug Enforcement Administration as excessive or abusive prescribing, and resulting in a statutory breach in prescribing protocols despite following the formulary, recommendation, and guidance of Shire Pharmaceuticals, therefore resulting in arrest and conviction, and significant damages upon such fraud.

IN DEFEAT OF SUMMARY JUDGEMENT:

Plaintiff, Tad Taylor, who brings this Cause against the named Defendant(s), challenges any formal attempt on behalf of the Defendants to seek and secure a ruling for Summary Judgement. "If the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party [Plaintiff] is entitled to a judgment as a matter of law." See Fed.R.Civ.P., 56(c).

When applying the standard, the court "views evidence and draws all reasonable inferences therefrom in the light most favorable to the party opposing Summary Judgment." See; Martin v. Kansas, 190 F.3d 1120, 1129 (10th Cir. 1999).

In the instant case, the Plaintiff points to previous rulings against such pharmaceutical manufacturers as Purdue Pharmaceutical, L.P. and others each who have failed in their attempt to procure Summary Judgment upon the overwhelming evidence brought to bear by the Plaintiff on misleading, fraudulent, and non-compliant trade practices and promotional materials relied upon by physicians and other prescribers.

In order to survive Summary Judgment by a Defendant, the Plaintiff must provide sufficient evidentiary material which raises a reasonable inference from which the fact finder may rationally conclude that the Plaintiff's injuries [in this instant case, formal conviction and loss of licensure and freedom], all "proximately resulted from the product's failure of performance causally related to its defective condition. See; Kaye v. Ronson Consumer Products, 1996 OK CIV, App. 57, 921 P.2d 1300, 1302 (OK 1996).

In this instant case, there existed a "Failure to Warn" precedence, to which, a Plaintiff must establish both cause-in-fact (the product or promotional material was outside of compliance), and proximate cause (the manufacturer of product 'breached a duty to warn of possible detrimental reactions'). As such, the Plaintiff may overcome any plea for Summary Judgment by the Defendant upon both "cause-in-fact" and "proximate cause."

CAUSE OF ACTION

LET THIS ACTION SHOW LIABILITY ON BEHALF OF DEFENDANT:

- a. Plaintiff, Tad Taylor, brings forward this first CAUSE OF ACTION upon the named Defendant(s) for failure to protect him as a prescribing physician tasked with representing the products, dosing requirements, safe prescribing levels, time-release guidelines, and all other protocols and standards in support of the efficacy of the Defendants' products, services, labeling, promotion, and physical effect on patients.
- b. Plaintiff, Tad Taylor, brings forward this second CAUSE OF ACTION upon the named Defendant(s) for their failure to provide certain warnings with regard to the use and application of their products as prescribed in accordance with the Manufacturer's acceptable guidelines and dosing which, upon comparison to the standards of compliance enforced under the FDA and the DEA, proved to far exceed such legal limits, therefore, compromising the integrity of this Plaintiff as prescribing physician to these standards.
- c. Plaintiff, Tad Taylor, brings forward this third CAUSE OF ACTION upon the named Defendant(s) for their aggressive and unorthodox sales, marketing, and promotional tactics and upon their assurances that such prescribing quotas fall within the guise of FDA and DEA compliance issues. That such tactics proved to be aggressive and overtly intimidating, and included an comprehensive incentive initiative camouflaged under various educational seminars, sponsorships, lunches, loyalty products, and other strategies designed to influence and encourage a proliferation of product prescriptions.

DEMAND FOR DAMAGES

MAY THIS COURT REVIEW SAID DEMANDS;

Tad Taylor, as Plaintiff, and upon certain Damages sustained as a direct result, actions and inactions, and both defective products and deceptive trade practices, provides a summation of harm, injury, and damage as prescribed herein;

DAMAGES SHALL INCLUDE;

COMPENSATORY, naming harm, injury, and damage to include, but may not be limited to; Arrest, Conviction, Lost License to Practice Medicine, Foregone Medical Practice, Lost Income, Lost Earnings, Missed Opportunity, Failed Investments, Seized Property, Seized Assets, Tainted Reputation, Status as Felon, All Future Income and Earnings, equal to an amount; Forty Four Million Dollars.....(\$44,000,000.00);

AND

AND

PUNITIVE, naming harm, injury, and damage to include, but may not be limited to; Loss of Freedom, Broken Relationships, Stress, Depression, Anxiety, Sleep Deprivation, Night Sweats, Nightmares, Loss of Appetite, Mental Anguish, Hopelessness, and PTSD, equal to an amount; Forty Four Million Dollars.....(\$44,000,000.00)

ADMINISTRATIVE, naming an obligation imposed upon the named Defendant(s) to be assessed all such Court Costs, Legal Fees, Filing Fees, Administrative Costs, and Plaintiff Expenditures assigned to the litigation of this Civil Matter.

PRAYER FOR RELIEF

MAY THIS HONORABLE JUDGE, PRESIDING, MOVE THIS CAUSE TO JURY TRIAL;

As Presiding Judge to this presentment and Cause, I hereby GRANT the Plaintiff the right to PROCEED TO JURY TRIAL upon the merits of his claim, and as foundational grounds to further explore expert testimony and evidence in support of the findings. That, upon such GRANT to PROCEED, this Court shall DISMISS the Defendants' Demand for Summary Judgement, and move this case forward accordingly.

AS	PRESCRIBED	ON	THIS	DATE:	: <u> </u>			,2021					
	SO SHALL I	IT E	BE ORI	ERED	ву	THE	COURT:		******	- 	ппск	PRESTITING	

SERVICE OF SUMMONS WAIVER

SERVICE SHALL BE WAIVED UPON THE FOLLOWING;

I, Tad Taylor, as named Plaintiff to this Cause, hereby WAIVE all such rights to the requirement for Service of Summons upon the named Defendant(s), and as provided, authorize this Court to provide said NOTICE under FORM 5 as the official 'NOTICE OF LAWSUIT AND DEMAND FOR RESPONSE" and FORM 6 which shall provide WAIVER of said NOTICE, therefore, and upon my signature, direct this Honorable Court and its Clerk to mail these forms, under official copy and service, to the named Defendant(s) at the address provided under Certificate of Service herein.

Upon the instance where the named Defendant(s) fail to sign and return the Waiver of Service of Summons under FORM 6, and within Thirty (30) days, the Clerk shall take appropriate action to place formal service, and shall further require that the Defendant(s) each pay the full cost of said service as prescribed under Fed.R.Civ.Procedure, so shall it be requested.

DATE OF WAIVER: $\frac{9-20}{}$, 2021

RESPECTFULLY REQUESTED BY: x _

CERTIFICATE OF SERVICE

LET THIS HONORABLE COURT TAKE NOTICE THAT;

Plaintiff, Tad Taylor, hereby declares and decrees that, the named Defendant(s) to this Cause have been notified upon receipt of a full and complete copy of the aforementioned Civil Complaint as placed with the United States Postal Service via First Class Mail and postage-paid, and all as timely and verified in accordance with the Mailbox Rule and the laws set forth under this jurisdiction.

FORWARDED TO:

SHIRE PHARMACEUTICALS 750 Chesterbrook Blvd. Wayne, PA 19807

SUBMITTED ON: 9-20

2021

RESPECTFULLY SUBMITTED BY: x

TAD TAYLOR, PLAINTIFF

VERIFICATION AND JURAT

WITH MY HAND AND SEAL ON THIS FILING:

I, Tad Taylor, as named Plaintiff to this Civil Complaint, hereby affirm and attest that the foregoing Petition shall stand as true and correct, and in knowing the laws and penalties of bearing false or misleading statements before my creator and fellow-man, I aver that all information presented has been conveyed with umberrima fidae, in good faith and with proper intention. All shall be adopted upon unsworn declaration and Title 28 U.S.C. §1746, and in accordance with judicial procedure as determined under §1731 thereof.

ON THIS DATE: 9-20 ,2021 anno domini

RESPECTFULLY SUBMITTED BY: X

TAD TAYLOR, PLAINTIES IN PRO-SE Federal Identification: 26966-078 Federal Correctional Institution

P.O. Box 9000

Seagoville, Texas 75159